REMARKS/ARGUMENTS

Claims 34-45 are pending.

The Examiner objects to claims 37-39 under 37 CFR 1.75(c) as being improper dependent form for failing to further limit the subject matter of the previous claim. The Examiner maintains that the claims are improper as they define the material being worked upon, while the independent claim is directed to an apparatus. The MPEP (Section 608(n)(III)) articulates an "Infringement" test to determine the propriety of dependent claims:

> The test as to whether a claim is a proper dependent claim is that it shall include every limitation of the claim from which it depends (35 U.S.C. 112, fourth paragraph) or in other words that it shall not conceivably be infringed by anything which would not also infringe the basic claim.

Claim 37 provides that the flowable material used in the thermal cycle molding module comprises a polymer. Claim 38 provides that the same flowable material comprises a selected material. Claim 39 provides that the flowable material comprises a gelatin. These claims do not negate or eliminate a feature recited in claim 34 from which they depend. In other words, dependent claims 37-39 include all of the elements of the base claim from which they depend.

Applicants are given broad discretion to define their inventions. Dependent claims can be drawn to inventions that would have different patent classification from that of the base claim. See MPEP 608(n)(III):

> The fact that a dependent claim which is otherwise proper might relate to a separate invention which would require a separate search or be separately classified from the claim on which it depends would not render it an improper dependent claim, although it might result in a requirement for restriction.
>
> The fact that the independent and dependent claims are in different statutory classes does not, in itself, render the latter improper. Thus, if claim 1 recites a specific product, a claim for the method of making the product of claim 1 in a particular manner would be a proper dependent claim since it could not be infringed without infringing claim 1. Similarly, if claim 1 recites a method of making a product, a claim for a product made by the method of claim 1 could be a proper dependent claim. On the other hand, if claim 1 recites a method of making a specified product, a claim to the product set forth in claim 1 would not be a proper dependent claim if the product might be made in other ways.

Claims 37-39 satisfy the "Infringement" test for being a proper dependent claim. Furthermore, Applicants are permitted to further define any feature of their invention. For these reasons, Applicants request that the Examiner reconsider and withdraw his objection to claims 37-39.

The Examiner rejects claims 34, 35, 37-39 and 41-44 under 35 U.S.C. 103 as being unpatentable over British patent specification GB 759,081 ("GB '081") when taken together with published US patent application 2002/0028240 ("Sawada et al."). The Examiner asserts that GB '081 discloses an apparatus for making a coated dosage form having a compression module, a transfer device for continuously transferring dosage forms to a second compression module. The Examiner asserts that Sawada discloses a device for manufacturing a coated dosage form by coating a preformed core by either compression coating or by an injection-molding module wherein the coating is melted to coat the previously formed core. The Examiner alleges that it would have been obvious to modify the apparatus shown in GB '081 to substitute an injection-molding die for the second compression-molding module since Sawada shows the processes to be alternatives. Applicants respectfully traverse these rejections.

Claim 34 is directed to a **linked apparatus** for making dosage forms containing a medicant having a compression module having means for forming compressed dosage forms by compressing a powder containing said medicant, a transfer device having means for continuously transferring said compressed dosage forms from said compression module to a

thermal cycle molding module, and a thermal cycle molding module having means for continuously molding a coating of flowable material over said compressed dosage forms. Claims 35, 37-39 and 41-43 depend ultimately from claim 34.

Claim 44 is directed to an **apparatus for making dosage forms** containing a medicant having a first rotor comprising a plurality of die cavities disposed around the circumference thereof so as to be carried around a first circular path by said rotor, a second rotor comprising a plurality of mold cavities disposed around the circumference thereof so as to be carried around a second circular path by said second rotor and a transfer device for transferring compressed dosage forms from said first rotor to said second rotor, said transfer device comprising a plurality of transfer units guided around a third path. Each of the die cavities has an opening for receiving powder and at least one punch mounted for displacement into said die cavity. Displacement of the punch into the die cavity compresses powder contained in the die cavity into a compressed dosage form. Each of the mold cavities is capable of enclosing at least a portion of a compressed dosage form and of receiving flowable material so as to coat a portion of the compressed dosage form. A first portion of the third path followed by the plurality of transfer units is coincident with the first circular path followed by the die cavities and a second portion of said the third path is coincident with the second circular path followed by the mold cavities.

GB '081 is directed to a machine for the production of coated tablets. The machine has a rotary tablet core making mechanism, a rotary coating mechanism, a rotary transfer mechanism for transferring a core tablet from the tablet core-making mechanism to the coating mechanism. The tablet core and tablet coating mechanisms are powder compression modules. The transfer mechanism is designed to move a compressed tablet core into a die containing additional powder for an additional compression step. Further, it is noted that the transfer mechanism travels a fixed circular path, which has a very limited coincident path for transfer.

Sawada is directed to a timed-release compression coated solid composition for oral administration. The written description of means for manufacturing the solid composition lacks any substance. For example, "the compression-coated layer can be easily prepared under ordinary conditions using an ordinary tabulating machine for making compression coated tablets or a compression-coating device." Second column for paragraph 87. Sawada continues:

> "methods that can ordinarily be used with hydrogel preparations are mentioned as other production methods. For instance, the extrusion molding method, injection molding method, etc. can be used whereby once a core containing the drug is made, the hydrophilic base, hydrogel-forming substance and when necessary, each additive are mixed with this core, and the mixture is melted over the core."

Sawada does not provide an enabling disclosure of an injection molding process for pharmaceutical/medicinal/nutritional dosage forms. Other than the unsupported reference to injection molding, there is absolutely no proof that those skilled in the art appreciated or understood how to incorporate the injection molding process into this specific field. There is no support for the assertion that compression molding and injection molding are seen as equivalent and interchangeable. For this reason, there is no basis for combining the teachings in GB '081 and Sawada as contemplated by the Examiner. Applicants request that the Examiner reconsider and withdraw his obviousness rejection of claims 34 and 44 in view of GB '081 and Sawada.

Claim 35, a dependent claim, further provides that the linked apparatus has means for operating the compression module, the transfer device, and the thermal cycle molding module simultaneously. Furthermore, as coatings are being molded on a first group of compressed dosage forms in the thermal cycle molding module, the transfer device transfers a second group of compressed dosage forms to the thermal cycle molding module, and the compression module forms a third group of compressed dosage forms. This claim describes the operating conditions in a preferred embodiment wherein each dosage form must complete two revolutions in the molding module before being ejected for further processing and packaging. GB '081 describes two compression modules, which could not accommodate multiple revolutions of dosage forms. The bare-bones disclosure of injection molding in Sawada does not provide any suggestion or motivation for such the process element recited in claim 35. Hence, even assuming the references could be combined, the result does not disclose or suggest the claimed invention of claim 35.

Claim 39 provides that the flowable material comprises a gelatin. As described more fully in paragraph 173 of our published application (US 2003/0068367 A1), gelatin presents a number of challenges above and beyond those exhibited by conventional thermoplastic materials. Gelatin is not discussed in Sawada. The molding module disclosed and taught in the instant application provides a solution to this problem. Therefore, the combination of GB

'081 and Sawada, even if proper, does not disclose or suggest the process defined by claim 39.

Claim 42 provides that the transfer device has a flexible conveying means traversing around a third path, a first portion of said third path being coincident with the first circular path followed by the plurality of die cavities, and a second portion of the third path being coincident with the second circular path followed by the plurality of mold cavities. The transfer mechanism shown in GB '081 is a rigid circular or rotary device. The transfer device disclosed and claimed herein is not limited to a circular path because of the flexible conveying means. This feature is a material element as the flexible conveying means increases the time or length of arc over which the first and second path are aligned with the third path. This extended overlap period improves accuracy in the transfer process and allows for greater speed and productivity. This features and attendant improved performance are not disclosed or suggested in the prior art.

The Examiner rejects claim 45 under 35 U.S.C. 103 as being unpatentable over GB '081 taken together with Sawada and further in view of an extract from the Injection Molding Handbook by Rosato ("Rosato"). The Examiner asserts that Rosato discloses heating and cooling systems in an injection-molding module wherein the mold cavities are heated and cooled by fluid passages. The Examiner alleges that it would have been obvious to modify the modified apparatus of GB '081 to include heating and cooling channels proximal to the mold cavity for the purpose of providing an improved surface to the molded article. Applicants respectfully traverse this rejection.

Claim 45, which depends from claim 44, provides that the apparatus has a heat source, a heat sink, and a temperature control system. The temperature control system has a tubing system that is disposed proximal to the mold cavities and is connected to the heat source and the heat sink for circulating heat transfer fluid, such that the mold cavities may be heated and cooled. Applicants were unable to find the figures referenced by the Examiner, though the text on page 189 referred only to the need for cooling. Rosato does not describe heating the mold cavities using the tubing system. Temperature control is especially important when injection molding using a gelatin-containing composition. Since Rosato does not describe all of the features recited in claim 45, the proposed combination does not render the claimed invention unpatentable.

The Examiner rejects claim 40 under 35 U.S.C. 103 as being unpatentable over GB '081 taken together with Sawada and further in view of U.S. Patent No. 5,213,808 ("Bar-Shalom"). The Examiner asserts that Bar-Shalom discloses an injection mold that forms a first injection-molded coating over an insert and a second injection molding coating of a different material over the insert. The Examiner alleges that it would have been obvious to further modify the apparatus in GB '081, which has been modified to replace the second compression module with an injection-molding module, to use a two-step injection mold that allows for coating an insert with different materials. Applicants respectfully traverse this rejection.

Claim 40 provides that the means for continuously molding a coating over said compressed dosage forms comprises (i) means for molding a first flowable material around first portions of said compressed dosage forms and (ii) means for molding a second flowable material around second portions of said compressed dosage forms. Neither GB '081 nor Sawada contemplate specific injection molding conditions or molding a distinct portion of the dosage form at separate times in the process. The Examiner does not contend otherwise. However, the Examiner maintains that the teachings in Bar-Shalom bridge the gap.

Bar-Shalom is directed to a controlled release article with pulsatile release. The processing described in column 11 appears to disclose an unspecified mechanism for injecting materials along with moving pistons and the creation of new cavities for introducing new layers through unseen openings. Bar-Shalom does not provide an enabling disclosure for one skilled in the art to produce an injection molding system for molding distinct portions of a dosage form. Additionally, there is no motivation for combining Bar-Shalom with GB '081 or Sawada because neither reference discusses injection molding in detail. Modifying the generic description of injection molding in Sawada to include molding portions of a drug dosage form is purely hindsight reconstruction of the invention of claim 40. Applicants request that the Examiner reconsider and withdraw his obviousness rejection of claim 40 in view of GB '081, Sawada and Bar-Shalom.

The Examiner indicates that claim 36 would be allowable if rewritten in independent form including all of the limitations of the base claim (34) and any intervening claims (none). Applicants submit that in view of the above remarks, the application is in condition for allowance. The Examiner is urged to contact the undersigned representative in the event that minor amendments will further prosecution.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

By: David R. Crichton

David R. Crichton
Reg. No. 37,300

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-6131
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